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Food and Agricultural Import Regulations and Standards

Allergen Labeling - Implementation November 25, 2005

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Report Highlights:

New food allergen labeling rules were introduced by Directive 2003/89/EC, an amendment to the general food labeling directive 2000/13/EC. The new rules will be fully implemented as from November 25, 2005. Products not complying with the new legislation will be prohibited for sale in the EU.

Includes PSD Changes: No
Includes Trade Matrix: No
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[E3]

Allergen Labeling – Implementation November 25, 2005

Legislation

New food allergen labeling rules were introduced by Directive 2003/89/EC, an amendment to the general food labeling directive 2000/13/EC. This directive requires food manufacturers to indicate 12 groups of potential allergens by reference to the source allergen if they are used as an ingredient at any level in pre-packed foods, including alcoholic drinks. The new rules also abolish the “25 percent rule” under which it was not mandatory to label components of compound ingredients if they made up less than 25 percent of the final food product. The new allergen labeling rules will be fully implemented as from November 25, 2005. Products not complying with the new legislation will be prohibited for sale in the EU.

List of potential allergenic ingredients to be labeled (Annex IIIa to Directive 2003/89/EC):

- Cereals containing gluten and products thereof
- Crustaceans and products thereof
- Eggs and products thereof
- Fish and products thereof
- Peanuts and products thereof
- Soybeans and products thereof
- Milk and dairy products (including lactose)
- Nuts and nut products
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/l expressed as SO₂

Exemptions

As a general rule, labeling derogations will not be allowed for allergenic ingredients. However, certain derivatives of the listed allergens may not trigger an allergic reaction. Directive 2003/89/EC establishes during a transitional period, a procedure that allows for a temporary exemption while food manufacturers conduct studies to provide the necessary scientific evidence. Directive 2005/26/EC establishes a list of allergen derivatives that, based on the European Food Safety Authority's risk assessments, are temporarily exempted - until November 25, 2007 - from mandatory labeling. Substances for which no final studies will have been delivered before the November 25, 2007 deadline will be re-included in the allergenic ingredients list.

List of allergen derivatives that are temporarily exempted (Annex to Directive 2005/26/EC):

Ingredients	Products thereof provisionally excluded
Cereals containing gluten	<ul style="list-style-type: none"> - Wheat based glucose syrups including dextrose - Wheat based maltodextrins - Glucose syrups based on barley - Cereals used in distillates for spirits
Eggs	<ul style="list-style-type: none"> - Lysozym (produced from egg) used in wine - Albumin (produced from egg) used as fining agent in wine and cider
Fish	<ul style="list-style-type: none"> - Fish gelatin used as carrier for vitamins or carotenoid preparations

	and flavors - Fish gelatin or Isinglass used as fining agent in beer, cider and wine
Soybean	- Fully refined soybean oil and fat - Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources - Vegetable oils derived phytosterols and phytosterol esters from soybean sources - Plant stanol ester produced from vegetable oil sterols from soybean sources
Milk	- Whey used in distillates for spirits - Lactitol - Milk (casein) products used in fining agents in cider and wines
Nuts	- Nuts used in distillates for spirits - Nuts (almonds, walnuts) used (as flavor) in spirits
Celery	- Celery leaf and seed oil - Celery seed oleoresin
Mustard	- Mustard oil - Mustard seed oil - Mustard seed oleoresin

Guidelines

General labeling directive 2000/13/EC sets out possible derogations for labeling "normal" ingredients. Although derogations are not allowed for allergenic ingredients, the Commission has published informal guidelines explaining why in some cases, derogations can also be admitted for such ingredients. The guidelines address questions relating to the indication or repetition of an ingredient and/or the source of that ingredient, the name under which the foodstuff is sold, the level of sulphur dioxide and the definition of "products thereof".

Examples:

- The label on a foodstuff sold under the name "cake flavored with almonds" could include the category name "flavor" alone in the list of ingredients, even where the flavor has been made using almond extracts because the name of the product clearly refers to the allergen ingredient concerned.

- A product containing additives, carriers and processing aids derived from wheat could be labeled as follows: "..., additive (1), carrier (1), processing aid (1),...(1) from wheat". The reference to the allergen ingredient from which the additives, carriers and processing aids originate must not be repeated as many times as these substances are present in the foodstuff.

The guidelines can be downloaded from the Commission's website at

http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/guidelines_6_10.pdf

References

European Parliament and Council Directive 2000/13/EC relating to the labeling, presentation and advertising of foodstuffs.

http://europa.eu.int/comm/food/fs/fl/fl01_en.pdf

European Parliament and Council Directive 2003/89/EC, amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs.

http://europa.eu.int/eur-lex/pri/en/oj/dat/2003/l_308/l_30820031125en00150018.pdf

Commission Directive 2005/86/EC establishing a list of food ingredients provisionally excluded from Annex IIIa of Directive 2000/13/EC.

[http://europa.eu.int/eur-](http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_075/l_07520050322en00330034.pdf)

[lex/lex/LexUriServ/site/en/oj/2005/l_075/l_07520050322en00330034.pdf](http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_075/l_07520050322en00330034.pdf)

(corrected by Commission Directive 2005/63/EC - http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/l_258/l_25820051004en00030003.pdf)

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E23186	New Allergen Labeling	September 2003
E35162	Food & Agricultural Import Regulations & Standards	August 2005
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